IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CIE, BAYER PHARMA AG and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 13-1272-RGA
WATSON LABORATORIES, INC.	)	
Defendant.	)	

PLAINTIFFS' ANSWERS TO DEFENDANT WATSON'S COUNTERCLAIMS

Plaintiffs Merck & Cie, Bayer Pharma AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") respond as follows to the Counterclaims filed by Defendant Watson Laboratories, Inc. ("Watson"). Answers to Watson's specific allegations are contained below in numbered paragraphs that correspond to the numbered paragraphs of Watson's Counterclaims. Bayer denies any allegations not expressly admitted in the Answer.

PARTIES

1. Watson Labs is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 311 Bonnie Circle, Corona, California, 92880.

ANSWER: On information and belief, Bayer admits the allegations of this paragraph.

2. On information and belief and based on Plaintiffs/Counterdefendants' allegations, Merck is a Swiss corporation having a principal place of business at Weisshausmatte 6460 Altdorf, Switzerland.

ANSWER: Admitted.

3. On information and belief and based on Plaintiffs/Counterdefendants' allegations, Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

ANSWER: Admitted.

4. On information and belief and based on Plaintiffs/Counterdefendants' allegations, Bayer Healthcare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

ANSWER: Admitted.

JURISDICTION AND VENUE

5. These counterclaims seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

ANSWER: Bayer admits that the Counterclaims purport to seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202. Bayer denies all remaining allegations in this paragraph.

6. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 35 U.S.C. § 271(e)(2).

ANSWER: Bayer admits that this Court has subject matter jurisdiction of these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a). Bayer denies all remaining allegations in this paragraph.

7. This Court has personal jurisdiction over Plaintiffs/Counterdefendants on the basis of, *inter alia*, their contacts with the District of Delaware relating to the subject matter of this action, including having filed this suit.

ANSWER: Bayer admits that, having filed this suit, it has submitted itself to the jurisdiction of this Court for the purposes of this case.

8. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Plaintiffs/ Counterdefendants' choice of venue.

ANSWER: Bayer admits that venue is proper under 28 U.S.C. § 1391. Bayer denies all remaining allegations in this paragraph.

BACKGROUND

9. This is an action based upon an actual controversy between the parties concerning the invalidity and noninfringement of U.S. Patent No. 6,441,168 ("the '168 patent") and Watson Labs' right to continue to seek approval of Abbreviated New Drug Application ("ANDA") No.

203593 for a drospirenone, ethinyl estradiol, levomefolate calcium product, and upon approval by the United States Food and Drug Administration ("FDA"), to manufacture, import, use, market, sell and/or offer to sell drospirenone, ethinyl estradiol, levomefolate calcium products in the United States.

ANSWER: Admitted.

10. Watson Labs submitted, and is continuing to seek FDA approval of, ANDA No. 203593. Watson Labs' ANDA No. 203593 seeks approval to engage in the commercial manufacture, use, and/or sale of products that Plaintiffs/Counterdefendants allege infringe the '168 patent.

ANSWER: On information and belief, Bayer admits the allegations of this paragraph.

11. The '168 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for the drug Beyaz®.

ANSWER: Admitted.

12. On information and belief, and based on Plaintiffs/Counterdefendants' allegations, Bayer Healthcare Pharmaceuticals Inc. is the holder of New Drug Application No. 022532 for Beyaz® tablets containing the active ingredients drospirenone, ethinyl estradiol, and levomefolate calcium.

ANSWER: Admitted.

13. Plaintiffs/Counterdefendants caused the '168 patent to be listed in the Orange Book in association with Beyaz®.

ANSWER: Admitted.

14. As a consequence of listing the '168 patent in the Orange Book, Plaintiffs/Counterdefendants were and are representing to the world that the '168 patent claims Beyaz®, and that patent infringement actions relating to the '168 patent could reasonably be expected to be brought against unlicensed filers of ANDAs containing a certification pursuant to FDCA Section 505(j)(2)(A)(vii), Paragraph IV.

ANSWER: Bayer admits that through its listing of the '168 patent in the Orange Book, Bayer was representing to the world that patent infringement actions relating to the '168 patent could reasonably be expected to be brought against unlicensed filers of ANDAs containing a certification pursuant to FDCA Section 505(j)(2)(A)(vii), Paragraph IV. Bayer denies all remaining allegations in this paragraph.

15. Watson Labs certified to the FDA in its ANDA No. 203593 that, in Watson Labs' opinion and to the best of its knowledge, its proposed drospirenone, ethinyl estradiol, levomefolate calcium products will not infringe any valid and/or enforceable claim of the '168 patent.

ANSWER: On information and belief, Bayer admits the allegations of this paragraph.

16. Watson Labs notified Plaintiffs/Counterdefendants of the factual and legal bases for Watson Labs' certification with respect to the '168 patent in a letter dated June 19, 2013 ("Notice Letter").

ANSWER: Admitted.

17. The Notice Letter included an offer of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

ANSWER: Admitted.

18. Plaintiffs/Counterdefendants have filed in this Court an infringement action to enforce the '168 patent.

ANSWER: Admitted.

19. Watson Labs has denied that it has, continues to, or will infringe, induce infringement of, and/or contribute to the infringement of, any valid and enforceable claim of the '168 patent.

ANSWER: Admitted.

20. Watson Labs has further asserted that the '168 patent is invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

ANSWER: Admitted.

21. In view of the foregoing, a conflict of asserted rights has arisen between Watson Labs and Plaintiffs/Counterdefendants with respect to the noninfringement and invalidity of claims of the '168 patent, and as to Watson Labs' right to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of its drospirenone, ethinyl estradiol, levomefolate calcium products. An actual controversy therefore exists between Watson Labs and Plaintiffs/Counterdefendants.

ANSWER: Bayer admits that an actual controversy exists between Watson Labs and Bayer regarding the validity and infringement of claims of the '168 patent. Bayer denies all remaining allegations in this paragraph.

FIRST COUNTERCLAIM – DECLARATION OF NON-INFRINGEMENT OF U.S. PATENT NO. 6,441,168

22. Watson Labs repeats and realleges paragraphs 1-21 of its Counterclaims as if set forth specifically herein.

ANSWER: Bayer repeats and realleges its answers to paragraphs 1-21 of the Counterclaims as if fully set forth herein.

23. Watson Labs does not infringe any valid, enforceable claim of the '168 patent, directly, indirectly, literally or under the doctrine of equivalents.

ANSWER: Denied.

24. The sale, offer for sale, manufacture, importation, or use of Watson Labs' drospirenone, ethinyl estradiol, levomefolate calcium tablets will not constitute infringement of any valid, enforceable claim of the '168 patent, either directly, indirectly, literally or under the doctrine of equivalents.

ANSWER: Denied.

SECOND COUNTERCLAIM – DECLARATION OF INVALIDITY OF U.S. PATENT NO. 6,441,168

25. Watson Labs repeats and realleges paragraphs 1-24 of its Counterclaims as if set forth specifically herein.

ANSWER: Bayer repeats and realleges its answers to paragraphs 1-24 of its Counterclaims as if fully set forth herein.

26. One or more claims of the '168 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

ANSWER: Denied.

DEMAND FOR JUDGMENT

The lettered Paragraphs following the heading "DEMAND FOR JUDGMENT" are requests for relief to which no response is required. To the extent any of these lettered Paragraphs are deemed to contain factual allegations, Bayer denies them and denies that Watson is entitled to any of the relief requested therein or to any relief whatsoever. Watson's requested relief should be denied in its entirety, with prejudice.

FIRST AFFIRMATIVE DEFENSE

To the extent that Watson seeks to invalidate any claim of the '168 patent based on grounds not articulated in its notice letter of June 19, 2013, but nevertheless publicly available as of that date, Watson is barred from relying on such grounds because it has unclean hands in that it did not exercise diligence in preparing its notice letter in accordance with the Hatch-Waxman statute.

SECOND AFFIRMATIVE DEFENSE

To the extent that Watson seeks to invalidate any claim of the '168 patent based on grounds not articulated in its notice letter of June 19, 2013, but nevertheless publicly available as of that date, Watson is barred from relying on such grounds under 21 U.S.C. § 355, including but not limited to 21 U.S.C. § 355(b)(2)(B)(3)(D).

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September 9, 2013

CERTIFICATE OF SERVICE

I hereby certify that on September 9, 2013, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 9, 2013, upon the following in the manner indicated:

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